



April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, Maryland 20852

0047 '03 APR -4 P3:51

Re: Docket No. 02N-0278 (Prior Notice)

Dear Sir or Madam:

BC Hot House Foods Inc. ("BCHH") welcomes this opportunity to comment on the U.S. Food and Drug Administration's proposed rule to require advance notice of all imported food shipments. BCHH markets, packs and distributes greenhouse grown fresh fruits and vegetables (i.e., tomatoes, bell peppers, cucumbers, and lettuce) on behalf of the sixty growers who share ownership in the private company. Our packing and distribution facility is located less than one hour from the United States border in Surrey (Vancouver), British Columbia, Canada. Last year, BCHH exported approximately U.S.\$ 69 million worth of highly perishable produce to the United States. BCHH, therefore, has a vested interest in the Agency's proposal to require prior notice of food imports.

BCHH appreciates FDA's efforts in implementing the several food-related provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act" or "Act"). We are concerned, however, that the Agency's proposed prior notice requirements would have a devastating effect on BCHH. We are a business that deals exclusively in the just-in-time delivery of highly perishable fresh fruits and vegetables. BCHH's ability to continue providing the prompt, responsive service required by its U.S. customers -- primarily grocery chains located throughout the U.S. -- would be severely compromised by the length of the proposed minimum prior notice deadline, as well as by the proposed restrictions on amendments to prior notice submissions. A shorter, rolling prior notice period, particularly for perishable products imported from Canada and Mexico, would alleviate

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significantly the burden of the prior notice requirement on BCHH and other importers of fresh produce from those countries. The comments below address these and additional concerns over various aspects of the proposal.

I. FDA Should Impose a Shorter, Rolling Minimum Prior Notice Deadline

BCHH strongly urges the Agency to establish no more than a four-hour minimum prior notice period for food imported into the U.S. through Canadian and Mexican border crossing ports of entry. In so doing, BCHH encourages the Agency to establish separate minimum prior notice time periods for different modes of transportation and/or different ports of entry. Shorter, rolling minimum notice periods would alleviate significantly the burden of the prior notice requirement on importers of fresh produce from Canada and Mexico. Moreover, it would provide importers with additional time in which to prepare and finalize prior notice submissions, thereby reducing the number of amendments and updates the Agency would have to process.

A. Effect of Proposed Minimum Prior Notice Period on BCHH

FDA's proposed prior notice deadline of noon the calendar day prior to arrival would essentially impose up to a 36-hour penalty on any importer who could not finalize all customer orders and submit prior notice by noon on any given day. A 36-hour delay in getting BCHH products to market would clearly result in lost and discounted sales: BCHH's highly perishable products have a very short shelf-life through its supply chain. Once displayed on the retailer's shelves, it has a mere 3-4 day shelf life before deterioration occurs. As an example, a 36-hour delay in shipping tomatoes would eliminate 40% of the shelf-life consumer level.

The business of importing highly perishable fruits and vegetables can only operate successfully on a strict just-in-time basis (from farm to retailer). The quality, value, and shelf-life of perishable fruits and vegetables begin to decline immediately after picking. Many customers expect to be able to place orders with BCHH on a daily basis to replenish the perishable produce they cannot otherwise store as inventory. Although the majority of our customers often submit initial orders for fresh produce daily and one day before the order is shipped from a BCHH facility, retailers routinely alter their orders within hours of the time the shipment is due to depart in an effort to meet their own customers' needs and just-in-time inventory requirements.

As demanded by the marketplace, BCHH regularly accommodates last minute changes to orders due to arrive at the border within several hours. The proposed minimum notice period would not allow this practice, however, straining customer relations and imposing an effective barrier to trade on products imported from foreign facilities located close to the U.S. border. Moreover, tying the prior notice period to a fixed time of day (i.e., noon) would force BCHH and its customers to finalize all orders shortly before noon each day since retailers would want to retain the maximum flexibility and complete ability to make last-minute changes to their orders (e.g., adding two pallets of tomatoes to an initial order for lettuce only) while receiving the freshest product available. As explained below, the realities of order completion would require BCHH, facing a noon submission deadline, actually to load all of its delivery trucks

shortly before noon, which would subsequently have to sit and wait until the prior notice period elapses at midnight before driving the 30 miles to the nearest border port of entry. Any orders that could not be finalized prior to noon would have to wait for 36 hours. Because BCHH operates on a 24/7 basis, this would severely diminish the volume of product it could ship to the United States.

The reason why trucks would be tied up by a noon submission deadline is that BCHH cannot finalize all customer orders until shortly before the delivery truck is ready to be loaded. As a business that necessarily operates on a just-in-time basis, BCHH does not maintain a steady inventory of produce at its packing and distribution facilities. We constantly are trying to match incoming customer orders to product availability from the greenhouses. Available produce is harvested daily, sent to our facility same day where it is packed and then loaded onto delivery trucks bound for the United States. The exact mix and quantity of fruit or vegetables coming in each day is known only through the packing and loading process itself. BCHH regularly will make product substitutions up to the moment of shipping, based both on the availability of product and on the customer's request. The finalization of an order and the loading of a truck thus take place almost simultaneously in many cases. A fixed noon deadline would create a crush of demand for truck capacity in the mornings, while a rolling deadline would permit BCHH to continue to serve the marketplace in a just-in-time manner.

B. Recommendations

BCHH understands and is willing to make changes to our business practices to accommodate the new prior notice requirements. FDA's proposal, however, would devastate our business by severely diminishing the volume of products we could export to the United States. To ensure the continued smooth flow of commerce into the United States, the Agency must allow for flexibility in the implementation of the prior notice rule and can easily do so by establishing separate minimum notification time periods for different modes of transportation and/or different ports of entry, as authorized by Congress.

The Bioterrorism Act specifically authorizes the Agency to consider, in determining the length of the prior notice period, among other factors: the effect on commerce; the locations of the various ports of entry into the United States; the various modes of transportation; and the types of food imported into the United States. The proposal, however, would apply the same minimum prior notice deadline to all foods, regardless of whether they are highly perishable, from Canadian or Mexican foreign facilities located close to the U.S. border, or destined for ports of entry where an FDA inspector is present on a regular basis.

A minimum notification deadline of four hours prior to the food's arrival at the port of entry for perishables and/or products traveling by truck or rail from foreign facilities located close to the U.S. border would provide the flexibility necessary to accommodate our customer's needs, while decreasing the number of amendments and updates that FDA would otherwise have to process. With respect to products transported by ocean carriers, BCHH recognizes that a longer minimum prior notice period may suffice.

BCHH also encourages the Agency to consider imposing shorter, minimum notification periods based on the individual port of entry. Noting that FDA inspectors are not stationed permanently at all ports of entry, the Agency states in the preamble that a minimum prior notice period of noon the calendar day before the food's arrival would be necessary "to ensure [the Agency] can plan and that its staff can travel to the arrival point . . ." While this may hold true for ports where there is no permanent FDA presence, it certainly does not extend to those ports where an FDA inspector is present on a regular basis.

BCHH imports the vast majority of its products – in the magnitude of 70 percent – into the U.S. through Blaine, Washington. This land border crossing port of entry is one of the most heavily utilized ports of importation of agricultural products into the western United States. We would expect FDA to regularly engage in inspection activities at the port. Therefore, if the Agency is not willing to reduce the minimum prior notice period for all ports of entry, BCHH would encourage the Agency to institute a shorter, rolling prior notice deadline for ports such as Blaine.

II. FDA Staff Should Be Available for Inspections on a Twenty-Four Hour Basis

BCHH strongly urges the Agency to make FDA inspection staff available 24 hours a day, seven days a week, for purposes of implementing and enforcing the prior notice requirements. It is our understanding, however, at least with respect to the port of Blaine, Washington, that FDA inspection staff is only available from 8 A.M. to 4 P.M., Monday through Friday. Such a limited schedule fails to address the needs of the food industry, which imports food into the United States 24 hours a day, seven days a week. Highly perishable fruits and vegetables cannot afford to be placed on hold for the weekend, or even overnight, while waiting for an FDA inspector to come on-duty. Placing entire shipments that arrive after business hours on hold for several hours or days while waiting for inspectors to return to their posts would cripple the flow of commerce into the U.S. and lead to a severe shortage of warehouse space.

III. FDA Should Allow for More Flexibility in Amendments to Product Identity

If FDA were to refuse our request to decrease the minimum required prior notice period, we would encourage the Agency to allow for more expansive amendments to product identity. Although the Agency's proposal would allow one amendment per prior notice to specify, among other things, the type of food (e.g., romaine versus iceberg lettuce), it is our understanding that importers would not be able to amend prior notice submissions to indicate changes to the nature of the food being imported (e.g., cucumbers versus lettuce). As explained above, however, importers of highly perishable fruits and vegetables routinely make changes to the nature of the food ordered well within twelve hours of the product's anticipated arrival at the port of entry. Because our customers do not and often cannot maintain large inventories of perishable produce, it is vital that they have the ability to fine tune their orders based on the needs of their own customers, which, at times, are unpredictable. BCHH urges the Agency to accommodate such business practices, which are somewhat unique to perishable foods, by allowing amendments to the nature of the food being imported, at least with respect to highly perishable foods such as fresh tomatoes and other fruits and vegetables.

It is our understanding that FDA's proposal would allow importers to submit "shell" prior notices, that would leave blank the last two digits of the product code, common or usual name of the food, lot or code numbers, quantity, and brand name, if that information could not be known with exact certainty by noon of the calendar day prior to arrival. The FDA product code consists of an industry code (e.g., "24" for vegetables/vegetable products), class code (e.g., fruit (veg) indicating a fruit used as a vegetable), subclass code (e.g., (plastic, synth)), process identification code ("PIC") (e.g., raw, fresh, refrigerated), and the product code (e.g., sweet peppers), which constitutes the last two digits of the FDA product code. The overall FDA product code for sweet peppers, cucumbers, and tomatoes is identical, depending on the type of packaging and PIC, except for the last two digits (e.g., 24 (vegetables/vegetable products) + F (Fruit(Veg)) + G (Plastic, Synth) + C (Raw, Fresh, Refrigerated) + __). If BCHH were to submit this incomplete FDA product code in its initial prior notice and note that an amendment would be forthcoming, it is our understanding that we would be able to amend the submission once it were certain that the products offered for import would be sweet peppers, tomatoes, and/or cucumbers, so long as the packaging/subclass code and PIC were the same. Because a different class code applies to lettuce, however, we would not be able to amend the initial prior notice to indicate that the product offered for import would be lettuce. ^{1/} It is difficult to fathom in the context of prior notice why FDA would allow sweet peppers, tomatoes, and cucumbers – but not lettuce – to be interchangeable for purposes of amendments.

BCHH believes that the Agency should be able to make a determination of whether or not to inspect an article of food based on the industry code and PIC, along with the other information provided in the prior notice, such as the submitter and shipper. Under this suggested approach, BCHH could submit notice to FDA that a raw, fresh, and refrigerated vegetable would be arriving at the port of entry at a certain time. ^{2/} The class, subclass, and product codes would be provided within two hours prior to the food's arrival to clarify the type of packaging used and whether the articles of food are sweet peppers, cucumbers, tomatoes, or lettuce. BCHH believes that this would provide FDA with sufficient time to revisit the issue of whether inspection is necessary and to send an inspector if one is not present at the port. If an inspector is not available within the two-hour time period, the Agency could always place the product on hold until one becomes available.

BCHH would also like to take this opportunity to seek clarification with respect to certain language found in the proposed regulation. Proposed Section 1.290(c), provides an example of an appropriate amendment involving peppers. The provision states that an FDA product code for "fresh peppers, refrigerated" could be submitted in an initial prior notice and later amended to specify the type of pepper that is the subject of the prior notice submission, i.e., "fresh green bell peppers, refrigerated." Based on a careful review of the interactive product

^{1/} The class code for lettuce is "T", which indicates a leaf/stem vegetable, while the class code for sweet peppers, cucumbers, and tomatoes is "F", which indicates fruits used as vegetables).

^{2/} Sweet Peppers, cucumbers, and tomatoes are grouped under the same industry code as lettuce (i.e., vegetables/vegetable products).

code builder found on FDA's website, however, there does not appear to be a product code for "green bell peppers." With respect to fresh bell peppers, the only applicable product code we found was "sweet peppers." The initial prior notice submission would, therefore, identify the product as "fresh, fruit used as a vegetable, refrigerated," not "fresh peppers, refrigerated." If the Agency is using a different product code builder, it should be made available to the public and the comment period should be extended accordingly. Otherwise, the final regulation should include a different example.

IV. FDA Should Allow Foreign Companies Designated as Importer of Record To Submit Prior Notice

BCHH strongly urges FDA to allow foreign companies that do not reside or maintain a place of business in the United States, but are designated by the U.S. Customs Service as an Importer of Record, to submit prior notice of food imports. The proposed rule would allow a purchaser or importer of an article of food who resides or maintains a place of business in the United States to submit prior notice, in addition to an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or U.S. importer, such as an import broker. FDA states in the preamble that it chose these U.S. entities because, among other reasons:

[the Agency believes] that it is the U.S. importer or U.S. purchaser who orders or buys the article of food, thereby initiating its importation into the United States. These persons thus should possess, or have the ability to obtain, the information required to be submitted in the prior notice within the time period in proposed Sec. 1.286.

Many foreign shippers and manufacturers act as Importer of Record for all products they ship to the United States and would, therefore, be the most appropriate entities to submit prior notice. It is not apparent from the proposal, however, that the Importer of Record for Customs' purposes is considered by FDA necessarily to be a U.S. importer. We, therefore, seek clarification on this point. If FDA does not intend the proposal to authorize Importers of Record who do not reside or maintain a place of business in the United States to submit prior notice, we urge FDA to reconsider.

Such designation would greatly simplify processing for foreign facilities, U.S. purchasers, and FDA. For instance, BCHH is the marketer, packer and distributor of the products we import into the United States. One of our delivery trucks may hold orders for five or more separate customers. If individual customers, as the purchasers of the product, were to submit independent prior notices for only their portion of a truckload destined for multiple customers, both BCHH and FDA would have to deal with five notices, not one. Further, one customer's mistake in a prior notice submission could result in the entire truckload being delayed or held by FDA, and BCHH would have to alert every single customer that submitted prior notice for a particular truckload if there were a need to update arrival information. Avoiding situations like this is the reason foreign shippers and manufacturers act as Importer of Record for

Customs purposes. The same logic argues that they would be the most appropriate entities to submit prior notice to FDA.

V. FDA Should Clarify When Grower Information Must Be Included in Prior Notice Submissions

The Bioterrorism Act requires prior notice submissions to include grower information, if known. The flexibility reflected by this requirement is essential. More than 60 growers deliver fresh picked fruits and vegetables to BCHH's central packing and distribution facility, where they are commingled and packed prior to distribution. It would be cost-prohibitive to separate production lots based on the identity of the individual grower(s) of the fruits or vegetables. Therefore, BCHH emphasizes the Act's "if known" qualification and encourages FDA to clarify that when grower information is not readily accessible to the importer, or impracticable to obtain, such information would not be required.

VI. Request for Clarification -- Consignee

BCHH requests clarification as to the definition of "consignee". Specifically, in the case where products are transferred to a contracted distribution center (that stores and ships product to customers), who would be the consignee?

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BCHH appreciates the opportunity to comment with regard to the Agency's proposed implementation of the Act's prior notice provisions. Please do not hesitate to contact us if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Jerome Woynarski /AMU". The signature is fluid and cursive, with the last name being the most prominent part.

Jerome Woynarski
Vice President, Operations
BC Hot House Foods Inc